REMARKS

I. Generally

By this amendment, Claims 1 and 5-7 have been amended. Claims 4 and 8 have been cancelled. Claims 9-28 have been added. The claims have been narrowed to the specific PEG-aspartic acid copolymer shown in Figure 2 for use as the immunologically invisible carrier. Applicants further note that the composition of matter claims have been added and comprise the same patentable invention as the kit claims based on the provisional double patenting rejection over US App. No. 09/982,287, which indicates that a kit comprising a composition is inclusive of the composition of matter of claim 1 of the '287 application. (March 17, 2003 Office Action, page 4).

II. Paragraphs 1-3 on page 2 of the office action

The Office Action requires modification of the title, abstract, priority claim paragraph, and addition of a brief description of the drawings section. All of these changes or additions have been made in the present amendment and response.

III. Rejection under 112(1)

The Office Action rejects the claims over several enablement and indefiniteness rejections. First, the Action rejects the claims as only being enabling for "a kit including a composition comprising a PEG copolymer with the structure depicted in the last structure of Fig. 1 coupled to an epitope," but not for all compositions comprising an immunologically invisible carrier coupled to an immunologically reactive substance. Without prejudice to further prosecution and to secure early allowance, Applicants have amended both independent claims to the novel PEG copolymer structure

shown in Fig. 2 coupled to an epitope, antigen, or antibody. Thus, the scope of the claims has been narrowed and it is respectfully asserted that the claims are enabled.

IV. Rejection under 112(2)

The Office Action rejects the claims under 112(2) for being incomplete and indefinite.

(a) Rejection for "omission of essential structural elements of the exact structure of the immunologically invisible carrier and points of attachment for the immunologically reactive substance and reporter moiety to the carrier" (March 17, 2003 Office Action, page 3).

The exact structure of the carrier is now specifically defined. The points of attachment are preferably at R for the epitope or other immunologically reactive substance as shown in Figure 2, but may be at any other location on the peptide where it can bind without steric hindrance. See page 7, line 32 through page 9, line 2. As explained on page 9, line 4 through page 10, line 2, the reporter moiety may be attached at R, when other units of the polymer have epitopes attached at their respective R locations, or at the N-terminus of the epitope peptides during the solid phase peptide synthesis. "By putting the reporter groups both on the polymer backbone and on the epitope peptides, the assay signal can be further enhanced (Figure 3)." Specification, page 9, lines 31-33. Thus, the specification has support for the points of attachment of both the substance and the reporter. Applicants request the withdrawal of this rejection.

(b) Rejection for "failing to distinctly claim the subject matter with respect to the use of the terms 'including' and 'comprising,' and that it is not clear what additional components are meant to be incorporated into the kit" (March 17, 2003 Office Action, page 3).

Applicants traverse this rejection. As with any kit, relevant reagents, tubes, or equipment may be included. Further, the reporter moiety may be included as part of the kit, and will be automatically included . before the beginning of the immunological assay where the carrier is

synthesized with the reporter attached (the one-step process as discussed in the specification on page 9, lines 4-8). Kits are commonly claimed using "comprising," which indicates that the elements listed are the essential elements of the kit. Recently issued biological patents using this "comprising" language with respect to kits include 6,605,705, 6,605,428, and 6,602, 885.

(c) Rejection for the term "epitope" being unclear (March 17, 2003 Office Action, page 4).

Epitopes are a part of an antigenic molecule to which the T-cell responds and a site on a large molecule against which an antibody will be produced and to which it will bind. Applicants direct attention to several places in the specification that clearly indicate that an epitope is typically smaller than and is only a fragment of a whole antigen. See, for example, page 3, lines 28-33 and page 4, lines 21-26 of the specification.

V. Provisional Obviousness Double-Patenting Rejections

Claims 1-8 are rejected over copending US Applications 09/982,287 alone or in combination with Zalipsky and over 09/982,300. Applicants own both of these applications and expressly abandoned 09/982,287 on August 15, 2003 and 09/982,300 on August 18, 2003. (A copy of both of those papers is attached to this office action.) Applicants have chosen to combine the kit claims of the pending application with composition claims previously covered in the other applications. Because those applications will not be pending upon the allowance of this case, this provisional rejection will be moot.

VI. Rejections under 102(a) and 103(a)

Finally, former claims 1-8 were rejected under anticipation and obviousness over Zalipsky (Bioconjugate Chem. [1995], 6, 150-165) and Fulton (USPN 4970300). These rejections are

inapplicable, particularly in light of the present claim amendments. Zalipsky describes a PEG carrier where "immunogenicity and antigenicity of proteins can be decreased." In fact, Zalipsky's entire approach to using PEG-protein conjugates is based upon the reduced immunogenicity and antigenicity. (See Table 1 of Zalipsky). In contrast, the present invention strives for the attached substances, which are preferably epitopes, to be immunologically active. In the case of the kit, the activity promotes the working of an immunological disease detection assay. Further, the PEG copolymers of the present invention are designed in a superior manner for their intended use as compared to standard PEGs because the carriers of the present have multiple attachment sites. Particularly, the PEGs of the present invention have the R attachment point, which is spaced to avoid steric hindrance with other attachments or functional groups. Thus, Zalipsky neither anticipates nor makes obvious the newly amended and newly added claims.

Further, Fulton is not applicable as an obviousness or anticipation reference. Fulton teaches an infusible conjugate of a protein with antihemophilic Factor VIII activity linked to a nonantigenic ligand. (See Fulton, Col. 4, lines 23-32). The Factor VIII conjugate from claim 1 coupled to standard PEGs of claim 2 do not teach or suggest the specific PEG-aspartic acid copolymer conjugated to epitopes, either as a composition, or in a kit, as described in the presently amended claims. Fulton's compositions for treating hemophilia are unrelated to the compounds and kit for immunoassays of the present invention.

Finally, none of the references cited as being cumulative to Zalipsky and Fulton are specifically relevant to the new and amended claims. Applicants respectfully request withdrawal of all pending rejections in light of the claim amendments and present comments.

CONCLUSION

The Commissioner is authorized to charge any fees required by the filing of these papers, and to credit any overpayment to Perkins Coie's Deposit Account No. **50-2586**. If anything can be done to further this application, please contact the undersigned at 310-788-9900.

Respectfully submitted,

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